UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

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Civil Action No.: 08 CV 2060 (JAP)

STATEMENT OF MATERIAL FACTS PURSUANT TO LOCAL RULE 56.1

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Oral Argument Requested
Motion Date: May 3, 2010

Pursuant to Rule 56.1 of the Local Civil Rules governing the United States District Court for the District of New Jersey, defendants, SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC, by their attorneys, Sedgwick, Detert, Moran & Arnold LLP, submit this statement of material facts as to which there are no genuine issues to be tried:

1. The ATB is a prescription medical device consisting of a metallic plate and four cancellous bone screws sold in a variety of lengths. (Ex. O)

2. The ATB is indicated for spinal fusion surgery for the treatment of lumbar and/or lumbosacral spine (L5-S1) instability resulting from, among other causes, degenerative disc disease. (See ATB Technique Guide, p. 2 at Ex. M)

3. Spinal fusion surgery involves an attempt to fuse two vertebrae together to reduce motion and pain in a diseased or injured segment of the spine. (See Deposition of Marc Levine, M.D., p. 15-16 at Ex. R)

4. The risk of a particular patient not achieving bony fusion across the intra-vertebral space is a well known and generally accepted in the field of spinal fusion surgery. (See Spielman Aff. ¶ 5 at Ex. H)

5. It is generally accepted in the fields of metallic internal fixation devices, biomaterials, orthopedics and fusion surgery that internal fixation devices are intended solely for temporary fixation, that no internal fixation device will last indefinitely and that internal fixation devices are subject to cyclical loading. (See Spielman Aff. ¶ 5 at Ex. H) These devices will ultimately fail in the presence of an incomplete fusion/nonunion. Id.

6. Each shipment of Synthes product came with an insert labeled "FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON" (the "Package Insert") that set forth the warnings that apply to all such metallic fixation devices. It stated:

- [t]hese implants are intended only to assist healing and not intended to replace normal bony structures.
- If there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue.
- Factors such as the patient's weight…,and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant.

- It is important to note that these implants may break at any time if they are subjected to sufficient stresses.
- These devices can break when subjected to the increased loading associated with delayed union or nonunion.
- Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed. (See Exhibit L) [Emphasis in original]

7. Plaintiff underwent anterior lumbar interbody fusion surgery on July 22, 2005 performed by Dr. Levine at St. Francis Medical Center. (See July 22, 2005 Operative Report at Ex. J) The surgery involved a Globus Medical 11 mm interbody device/spacer, 2 Medtronic Infuse sponges and a Synthes ATB. (Id.)

8. Plaintiff's relevant medical history shows that he is a 47 year-old man with a pre-surgical history of lower back pain with radiation stemming from multiple back injuries that occurred between September 1998 and August 2004 while he was working as a corrections officer. (See Ex. P – SYNTH000203-SYNTH463)

9. In March 2004, after years of unsuccessful treatment with steroid injections, plaintiff began treating with Dr. Marc Levine of Trenton Orthopaedic Group. (SYNTH000218 at Ex. P)

10. At that time, plaintiff testified that his lower back "would throb, tightening and stabbing pain, and it would go down my right leg…It was steadily getting worse." (Jones Dep., p. 116 at Ex. Q)

11. Dr. Levine made an initial diagnosis of low back pain with degenerative disc disease at L5-S1 as well as congenital stenosis at L4-5 to a greater degree than L3-4. (SYNTH000218 at Ex. P)

12. In July 2004, following another injury at work, plaintiff testified that his pain level had increased from "moderately severe to falling-down-crying severe." (Jones Dep., p. 125 at Ex. Q) His overall pain distribution was now 80% low back and 20% right leg whereas it had previously been 60% lower back and 40% right leg. (SYNTH000219 at Ex. P)

13. In an August 23, 2004 office note, Dr. Levine wrote that plaintiff's "low back pain is significant enough that he wishes to pursue surgical intervention. The pain is so severe that the other day he left his children to go upstairs to lay down so that he would not cry in front of them. The pain is severe regardless of occupation." (SYNTH000257 at Ex. P)

14. In August 2004, in order to determine a course of surgical treatment (decompression v. fusion surgery), Dr. Levine ordered that a discogram be performed on plaintiff. (SYNTH000259 at Ex. P)

15. The August 2004 discogram showed that plaintiff had multi-level disc disease with pain of 7 out of 10 to 10 out of 10 at several levels of his spine. The discogram report documents the following: 1) L2-3 with grade 0 anular degeneration and disruption; mild discorant back pain; 2) L3-4 with grade II anular degeneration and grade II disruption; concordant low back, right buttock and upper leg pain (7/10); 3) L4-5 with grade 0 anular degeneration and disruption; no pain; and 4) L5-S1 with grade I anular degeneration and focal grade III disruption; exact low back and right leg pain (10/10). (SYNTH000415-418 at Ex. P)

16. Following the discogram, Dr. Levine discussed with plaintiff performing an L5-S1 anterior lumbar interbody fusion. He testified that the surgery is considered successful if a patient "had improvement of 50 percent of their pain." (Levine Dep., p. 42 at Ex. R) Dr. Levine also specifically informed plaintiff that the findings of disc disease at other levels of his spine "could cause residual pain, even despite surgery at the L5-S1 level." (Levine Dep., p. 58) He also warned plaintiff that he may not be able to return to work as a corrections officer. (Levine Dep., p. 59-60)

17. Dr. Levine discussed with plaintiff that attempting to fuse the L5-S1 vertebrae would not alleviate plaintiff's discomfort and the pathology at the L3-L4 level. (SYNTH000257 at Ex. P) Dr. Levine noted that "there may be some residual discomfort from that pathology in the future." (Id.) Plaintiff testified that he recalled these discussions and knew the goal of the surgery was to alleviate rather than eliminate his pain. (Jones Dep., p. 238-239 at Ex. Q)

18. Plaintiff decided to proceed with surgery with Dr. Levine. He understood that the goal of the surgery was to reduce rather than eliminate his pain. (SYNTH000252 at Ex. P)

19. Dr. Levine specifically warned plaintiff about the risks of the surgery including "failure of fusion" and "failure of the instrumentation." (Levine Dep., p. 51-52 at Ex. R; SYNTH000257 at Ex. P)

20. Dr. Levine performed surgery on plaintiff on July 22, 2005 at St. Francis Medical Center. The surgery involved: 1) an L5-S1 anterior diskectomy where the disc between the L5-S1 vertebrae was removed; 2) an L5-S1 anterior lumbar interbody fusion where a non-Synthes, Globus 11 mm interbody device was inserted in place of the removed disc along with 2 Infuse

sponges containing material designed to encourage fusion and bone growth in the vertebral space; and 3) the implantation of the Synthes ATB system at L5-S1 consisting of a 41 mm plate, two 24 mm screws and two 26 mm screws to provide supplemental support for the interbody device and graft material. (See July 22, 2005 Operative Report at Ex. J)

21. Between August 2005 and May 2006, plaintiff had multiple follow-up visits with Dr. Levine to track his progress. On August 8, 2005, Dr. Levine noted that plaintiff was "doing quite well overall." (SYNTH000250 at Ex. P)

22. On September 8, 2005, a x-ray showed that the instrumentation was in place. (SYNTH000249 at Ex. P) Plaintiff reported pain but was "dramatically improved" and "even on his worse days, was better than it was on his best day prior to surgery." (Id.)

23. On October 24, 2005, plaintiff stated to Dr. Levine that he still gets some aches and pains in his back as well as his legs. An x-ray showed "good placement of the graft as well as instrumentation." (SYNTH000248 at Ex. P)

24. On December 5, 2005, almost six months post-surgery, plaintiff reported that "prior to surgery his biggest complaint was right sided back pain and some right buttocks pain, which has largely resolved…he is having some left low back pain and some left buttocks pain." (SYNTH000247 at Ex. P) An x-ray showed the instrumentation was still in place. (Id.)

25. A February 9, 2006 note stated plaintiff reported "that physical therapy has been going well although he is still having low back discomfort." (SYNTH000245 at Ex. P)

26. On April 13, 2006, plaintiff reported to Dr. Levine that "his back pain continues to be tremendously improved following surgery." (SYNTH000239 at Ex. P) He was started on

a work hardening program to see if he would be able to return to work. It was noted that plaintiff still had lower extremity symptoms during work hardening. (Id.)

27. On April 18, 2006, plaintiff reported to Dr. Levine that he "had the onset of back pain after bending over with numbness and tingling going down his legs." (SYNTH000238 at Ex. P) An x-ray taken that day showed "the instrumentation to be in place. There is no evidence of retropulsion of his PEEK device or retropulsion of the screws into any canal region." (Id.) Dr. Levine prescribed steroids and suggested that plaintiff reduce the level of his physical therapy. (Id.)

28. A May 11, 2006 note from Dr. Levine states plaintiff "is still having some concerns regarding numbness and tingling predominantly in the back of the thighs of both legs. He also has some numbness in the feet. The numbness and tingling in the thighs is constant. He reported an event 2-3 weeks ago where he heard a snap in his back while bending with increased symptoms in his legs." (SYNTH000237 at Ex. P)

29. An x-ray taken on May 11, 2006 showed "a failure of the left S1 screw of the ATB system with breakage within the bone." (SYNTH000237 at Ex. P)

30. Dr. Levine is of the opinion that complete bony fusion had not occurred in the ten month period following surgery which allowed enough micromotion to be present to cause a failure of the screws. (Levine Dep., p. 90, 94 at Ex. R)

31. Dr. Levine's contemporaneous office notes confirm his view that the failure to achieve complete bony fusion caused breakage of the screws. A May 18, 2006 note from Dr. Levine, following a CT scan of the lumbar spine, states: "based on the broken hardware, we have

to assume that the fusion is not yet solid. For this reason, I am recommending a posterior stabilization procedure…" (SYNTH000236 at Ex. P) A follow-up note dated June 8, 2006 states that "the belief is to proceed with posterior stabilization for this anterior construct that may have some motion which would explain the failure of the plate screw." (SYNTH000234 at Ex. P)

32. On June 26, 2006, plaintiff saw Dr. Levine again. An x-ray taken on June 26, 2006 showed "breakage of both screws at the S1 level." (SYNTH000233 at Ex. P) A CT Scan report that was reviewed by Dr. Levine showed "some evidence of fusion mass within the interbody device" but it was difficult to fully assess because the plate was blocking the x-rays. (Id.) Dr. Levine further noted "probable micro motion at the L5-S1 level." (Id.) The CT report stated that "I cannot clearly demonstrate bony bridging anteriorly." (Id.) This meant that complete bony fusion of the L5-S1 vertebrae had not occurred almost a year after surgery. Dr. Levine recommended proceeding with the implantation of posterior spinal instrumentation at L5-S1 with percutaneous pedicle screws. (Id.)

33. On August 4, 2006, plaintiff underwent posterior spinal fusion surgery by Dr. Levine at Robert Wood Johnson University Hospital (See August 2006 operative report at Ex. K)

34. As of his deposition on February 2, 2009, plaintiff reported that his pain was different but better than before the surgery. (Jones Dep., p. 218 at Ex. Q) He rated his pain as a 3 out of 10 while prior to surgery he rated the pain as 7 or 10 out of 10. (Jones Dep., p. 212-218 at Ex. Q)

35. The purpose of the ATB was to provide supplemental support for the interbody device and graft material that was inserted in place of the removed disc. (Levine Dep., p. 19 at Ex. R; Spielman Aff. ¶ 13 at Ex. H)

36. Spinal fusion can be achieved with an interbody device and graft material and no additional hardware. (Levine Dep., p. 18)

37. The Globus interbody device as well as the ATB remained in alignment before and after the breakage of the screws. (See Levine Dep., p. 92-93 at Ex. R, SYNTH000232-000234; 000238 at Ex. P)

38. The instrumentation, including the broken Synthes' screws which remain, are not impinging on any of plaintiff's nerves and are unrelated to plaintiff's current complaints of pain. (Levine Dep., p. 79 at Ex. R)

39. Plaintiff's expert Warren Lieberman is a metallurgical engineer who spent thirty-four years of his career at the Boeing Company responsible for airplane design. (See Lieberman CV at Ex. E)

40. Mr. Lieberman is neither a physician nor a spine surgeon. (Lieberman Dep., p. 12 at Ex. S) He has never consulted or testified before on any implantable surgical device case. (Id. at 29) He does not have any education training or experience in the field of medical devices. (Id. at 35) He has never been employed by or consulted for a company that designs, manufactures or tests medical devices. (Id. at 35) He has never designed a medical device. (Id. at 35-36) He has never conducted a clinical trial of a medical device. (Id. at 37) He is not a member of any professional organizations that deal with medical devices. (Id. at 36) He has

never published any scientific papers with respect to medical devices. (Id. at 36) He has never studied and has no formal training in the field of biomechanics. (Id. at 8, 21) He has never studied the application of metal in an implantable surgical device. (Id. at 9) He has no formal training in orthopedics and has never observed a surgical procedure. (Id. at 20) He has never taught or given any lectures on spinal surgery, orthopedic surgery, medical devices, biomechanics or the effect of blood, body tissue and bone on implantable surgical devices. (Id. at 22-23) He has never written any peer reviewed articles on these topics. (Id. at 23) Mr. Lieberman has no expertise in testing implantable medical devices or analyzing the cause of the breakage of a surgical screw. (Id. at p. 147, 150)

41. Mr. Lieberman has no expertise with respect to the steps a surgeon takes to implant a spinal fusion device. (Id. at 39) He has no expertise with respect to how spinal fusion surgery is supposed to reduce a patient's pain. (Id. at 53-54)

42. Mr. Lieberman has never studied medical journals, orthopedic textbooks or other materials about the race to fusion. (Id. at 59-62)

43. Mr. Lieberman has never heard of the term stress shielding. (Lieberman Dep., p. 64 at Ex. S)

44. Stress shielding is a concept that in designing a medical device to aid fusion you do not want to make the device so strong that the load will be borne entirely by the device rather than the bones. (Spielman Aff., ¶ 14 at Ex. H; Zardiackas Aff. ¶ 8 at Ex. I)

45. The interbody device/spacer that was used by Dr. Levine is the key part of achieving fusion. (Levine Dep., p. 16-20 at Ex. R; Spielman Aff., ¶ 8 at Ex. H)

46. Mr. Lieberman's alternative design plan for shot peening exists solely in his mind and has not been committed to paper. (Lieberman Dep., p. 77-78 at Ex. S)

47. Mr. Lieberman cannot state to what extent shot peening would have improved the fatigue life of the ATB screw. (Lieberman Dep., p. 86, 124 at Ex. S)

48. Mr. Lieberman also has not tested whether shot peening the screw, i.e. making it stronger, may negatively affect bone growth and fusion in a patient through a process known as "stress shielding". (Lieberman Dep., p. 182-183 at Ex. S)

49. A surgeon does not want a device that will shield the graft site from loading. This is called stress shielding where the device, rather than the graft site, handles the majority of the load that a person places on his spine. It is generally accepted that stress shielding inhibits rather than aids fusion. (Spielman Aff. ¶ 14 at Ex. H; Zardiackas Aff. ¶ 8 at Ex. I)

50. Mr. Lieberman has not ruled out whether a cancellous bone screw, like the screws used in the ATB, could be shot peened without damaging the specially-designed threads of the screw which are crucial for obtaining purchase within the bone. (Lieberman Dep., p. 221-222, 265-267 at Ex. S)

51. Shot peening has a high potential to damage the threads of a cancellous bone screw, it has never been validated for such use with cancellous bone screws and Mr. Lieberman is not aware of another manufacturer which used the process for cancellous bone screws. (Zardiackas Aff., p. ¶ 13 at Ex. I)

52. Gray anodization is a process that imparts a gray color to the surface of a device, imparts increased lubricity, and increases the fatigue strength of titanium. (Zardiackas Aff. ¶17 at Ex. I)

53. Mr. Lieberman has done no testing to validate whether the use of gray anodization would be feasible, safe or would improve the fatigue life of cancellous bone screws of the type used in the ATB. (Lieberman Dep., p. 274, 284 at Ex. S)

54. Imparting a gray color to all of Synthes surgical screws via anodization would interfere with Synthes' ability to color code its implants and thus increase the risk of sizing errors. Further, it could negatively affect the holding power of the screws in bone because of the increased lubricity caused by anodization. (Zardiackas Aff. ¶ 17 at Ex. I)

55. Dye penetrant inspection is a process that involves using dye penetrants to detect the presence of surface defects, including cracks on forged and cast medical devices which are much larger and have less tortuous surface profiles than ATB screws.

Mr. Lieberman is not aware that dye penetrant inspection has ever been used for surgical screws. (Lieberman Dep., p. 223) He is not aware of any company that makes screws for use in spinal fusion that performs dye penetrant inspection of the screws. (Lieberman Dep., p. 223, 229)

56. Ultrasonic testing, which is performed by Synthes' titanium suppliers, looks at not just the surface like a dye penetrant inspection, but instead, examines the totality of the metal. (Lieberman Dep., p. 225, 277)

57. Mr. Lieberman cannot identify a flaw within the screws implanted in Mr. Jones because the ATB screws remain in plaintiff.

58. Mr. Lieberman has performed no analysis as to whether it is feasible or safe to use dye penetrants on a screw meant for implantation in the human body. (Lieberman Dep., p. 238 at Ex. S)

59. Mr. Lieberman has not done any testing to determine whether you can dye penetrant test the ATB screws and completely remove the chemical residue from the screws. (Lieberman Dep., p 268)

60. Mr. Lieberman is not aware of whether the solvents used in dye penetrant testing are biocompatible with humans. (Lieberman Dep., p. 271-272)

61. Dye penetrant testing is not feasible or safe for surgical screws of the type used in the ATB. (Zardiackas Aff. ¶ 15-16 at Ex. I)

62. Synthes tested the ATB, as per industry and FDA standards, by running both a static axial test and a dynamic axial compression/tension fatigue test to 10,000,000 cycles. (See ATB test results at Ex. O: SYNTH001738 – SYNTH 1742; Deposition of Benjamin Barrall, p. 60-62 at Ex. T)

63. Mr. Lieberman is not aware of a single government or industry standard Synthes allegedly violated in its testing of the ATB prior to its introduction.

64. Mr. Lieberman is not aware of a test that could account for all the variables that a device may encounter after it is implanted in a patient. (Lieberman Dep., p. 158-159 at Ex. S)

65. It is not possible to determine how long an internal fixation device will last either as a function of time or as a number of cycles because the load for each cycle imposed on the implant by an individual cannot be determined. The reason for this dilemma is that no two

patients have the same anatomy or physiology, nor do they impose the same variable load spectrum on a device which has been implanted. (Zardiackas Aff. ¶ 4 at Ex. I)

Dated: New York, New York
February 26, 2010

Respectfully Submitted,

By: /s/ Christopher J. Keale

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